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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,342	05/26/2000	YUKIO KATO	046124-5025	3974

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/26/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,342

Applicant(s)

KATO ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13, 15-17, 19-21 and 25-38 is/are pending in the application.
- 4a) Of the above claim(s) 11-13, 19-21, 33 and 35-38 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25 is/are allowed.
- 6) ☒ Claim(s) 15-17, 26-28, 32, 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 15-17, 25-28, 32 and 34, primers of SEQ ID NOs: 21 and 22 are examined in the instant application.

Claim 25 seems to be free of prior art and is allowable.

PRIORITY DATE

Applicant asserts that the 17 pages of sequence listing of the PCT application filed on May 26, 2000 contains 22 sequences, including the instant SEQ ID NOs: 21 and 22.

Applicant further asserts that at the very least the priority date for claim 34 is the filing date of the PCT application, or Nov. 27, 1998.

Applicant asserts that although the specific example in the specification exemplifying the use of primers having the sequences of SEQ ID NOs: 21 and 22 was not included in the Japanese priority application 1997-342060, filed Nov. 27, 1997, as evidenced by translation submitted March 19, 2002. Applicant asserts that the Japanese priority document recites that DNA can also be obtained from chromosomal DNA by hybridization or PCR using a probe or an oligonucleotide primer prepared based on the base sequence and that alternatively, the DNA can be obtained by carrying out RT-PCR using cartilage mRNA. Applicant asserts that the Japanese priority document thus fully discloses the limitation of claim 34.

Applicant's arguments in paper No:16 have been considered but are found not to be persuasive for the following reasons:

The priority date for claim 34 is still determined to be May 26, 2000 for the following reasons:

Although the PCT application filed on May 26, 2000 contains 22 sequences, including the instant SEQ ID NOs: 21 and 22, and although the Japanese priority document recites that DNA can also be obtained from chromosomal DNA by hybridization or PCR using a probe or an oligonucleotide primer prepared based on the base sequence and that alternatively, the DNA can be obtained by carrying out RT-PCR using cartilage mRNA, there is no teaching in said PCT application and the Japanese priority document that the claimed nucleic acid molecule is obtained by PCR or RT-PCR amplification using specifically SEQ ID NOs: 21 and 22 as primers.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER

Claim 34 remains rejected under 35 USC 112, first paragraph, pertaining to new matter, for reasons already of record in paper No:15.

The same arguments and reasons for rejection set forth under priority date apply here as well.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

Claims 26, 28, 32 remain rejected under 35 USC 112, first paragraph, for lack of a clear written description of a "fragment" that encodes at least ninety consecutive

amino acids of SEQ ID NO:2, or a "fragment" that is complementary to a nucleic acid which encodes at least ninety consecutive amino acids of SEQ ID NO:2, for reasons already of record in paper No:15.

Claims 15-17, 27 are rejected for lack of enablement of a clear written description of a "gene" or a "DNA sequence" encoding SEQ ID NO:2 or variants thereof having Rho-GEF activity, for the same reasons already of record in paper No:15.

Applicant argues that the rejection is moot in view of the amendment of the claims to recite a nucleic acid molecules encompassing fragments which encode at least ninety *consecutive* amino acids of SEQ ID NO:2 and complements thereof.

Applicant's arguments in paper No:16 have been considered but are found not to be persuasive for the following reasons:

Rejection remains, because the claims 26, 28, 32 encompass unrelated sequences that share with the claimed nucleic acid molecule a fragment that encodes at least ninety *consecutive* amino acids of SEQ ID NO:2, e.g., a nucleic acid sequence encoding the protein taught by Rosen et al, of record, which share with the claimed nucleic acid molecule a fragment that encodes at least ninety *consecutive* amino acids of SEQ ID NO:2.

Further, claims 15-17, 27, 32 encompass genomic DNA sequence, the structure of which is not described in the specification.

The specification fails to identify and describe the 5' and 3' regulatory regions and untranslated regions essential to the function of the claimed invention, which are required since the claimed invention currently encompasses the gene. The art indicates

that the structures of genes with naturally occurring regulatory elements and untranslated regions is empirically determined (Harris et al.; Ahn et al.; and Cawthon et al, all of record). Therefore, the structure of these elements is not conventional in the art, one of skill in the art would therefore not recognize from the disclosure that applicant was in possession of a gene or a DNA sequence encoding the amino acid sequence of SEQ ID NO:2 or a variant thereof.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

1. Claims 16-17 remain rejected under 35 USC 112, first paragraph, for lack of enablement for a DNA sequence encoding a "variant" protein having Rho-GEF activity, and hybridizing under stringent conditions with nucleotide sequences from 49th to 3,183th bases of SEQ ID NO:1, for reasons already of record in paper No:15.

Applicant argues that the rejection is moot in view of the amendment of the claims to recite the function of the claimed variants having Rho-GEF activity.

Applicant's arguments in paper No:16 have been considered but are found not to be persuasive for the following reasons:

Rejection remains, because although one could screen for the variant proteins, Applicant has not shown how to make the claimed variants.

2. Claims 15-17, 32 remain rejected under 35 USC 112, first paragraph, for lack of enablement for a gene or a DNA sequence encoding the amino acid sequence of SEQ ID NO:2 or a variant thereof, for reasons already of record in paper No:15.

It is noted that claims 15-16 were inadvertently omitted in the rejection. It is clear that claim 15-16 should have been included with claims 17, 32 because they all are directed to a gene or a DNA sequence encoding the amino acid sequence of SEQ ID NO:2 or a variant thereof, and the issue remains the same.

Applicant recites Sambrook et al.

Applicant argues that the gene encoding a CDEP protein could be isolated following the methods known in the art.

The recitation of Sambrook et al is acknowledged.

Applicant's arguments in paper No:16 have been considered but are found not to be persuasive for the following reasons:

Rejection remains, because although one could screen for the claimed gene or DNA sequence, Applicant has not shown how to make the claimed gene or DNA sequence, because the structure of which is not known and not predictable, as taught by Harris et al, Ahn et al, Cawthon et al, all of record.

REJECTION UNDER 35 USC 102 (b)

Claim 34 remains rejected under 35 USC 102(b) as being anticipated by Koyano, y et al for reasons already of record in paper No: 15

Applicant argues that claim 34 is entitled to a foreign priority date of November 27, 1997, and that the recited reference was published in December 18, 1997.

Applicant's arguments in paper No:16 have been considered but are found not to be persuasive for the following reasons:

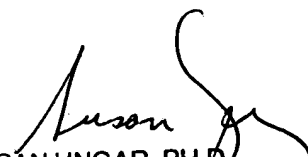
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Rejection remains, because claim 34 is not entitled to a foreign priority date of November 27, 1997

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.


SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

MINH TAM DAVIS

August 21, 2003